VERMONT
DEPARTMENT OF HEALTH

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Vaccine Storage and Handling Standard Operating Procedures (SOP)

(Revised January 2020)

Vermont Immunization Providers

This Vaccine Storage and Handling SOP is based on the CDC Vaccine Storage and Handling Toolkit and "You Call the Shots" webinars. It provides information for proper management of publicly-funded vaccine. Use of this template assures that vaccine is managed according to VCVP/VAVP and Vermont Immunization Program requirements. Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

Date Reviewed	Name & Credentials	Webinars Viewed

Vaccine Storage and Handling SOP

Practice Name _____

PIN# _____

Vaccine Coordinators (see page 3)		
Name	Role (e.g. RN, MA)	Home and/or Cell Phone
Vaccine Coordinator:		
Back-up Coordinator:		
2nd Backup Coordinator (*optional*):		

Alternate vaccine storage and backup data logger	
Location name	
Location address	
Phone	
Primary contact person off-hours phone #	
Backup DL Location	

Regional Immunization Specialist	
Name	
Phone number	
Email address	

Supplies Needed to Transport Vaccine (check all available on site)	
Hard sided cooler	
Backup Data Logger	
Frozen Water Bottles	
Cardboard and bubble wrap	

Person Completing This Form	
Date of completion	
Your Name	
Title	
Your Signature	

Whenever there are changes, contact the Immunization Program at 802-863-7638

Additional Information (use as needed)	

Abbreviations:
ACIP: Advisory Committee on Immunization Practices
MMR: measles, mumps, and rubella vaccine
MMRV: measles, mumps, rubella, and varicella vaccine
VDH: Vermont Department of Health
VCVP: Vermont Child Vaccine Program
VAVP: Vermont Adult Vaccine Program
VIMS: Vaccine Inventory Management System

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I. Vaccine Emergency Management

A. Temperature excursions

If you experienced a temperature excursion, contact the Immunization Program during the standard business hours promptly by phone 1-800-640-4374 or email ahs.vdhimmunizationprogram@vermont.gov

- Do not move vaccine without approval.
- Place all vaccine of questionable quality on hold in storage (*as if* it is still viable), but do not use until guidance is obtained from the Immunization Program. Refrain from making assumptions about vaccine spoilage.
- Correct obvious problems. For example, if the door is ajar – close it; if the unit is unplugged – plug it in (do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator quickly, as this may lead to overcompensation and freezing).
- Reconcile your vaccine inventory in VIMS if it has been longer than 3 months since last reconciliation.
- Acknowledge the alarm in the cloud system after the issue has resolved and note actions that you took. Once the alarm is confirmed with the needed documentation, you will not be able to add to at a later time(see section D for guidance).

After standard business hours contact the on-call person for guidance if you need to use the vaccine before the next business day or if you need to move the vaccine. Otherwise, contact the Program the next business day.

Never move vaccine without prior approval from the Immunization Program

Failure to seek and follow VDH guidance for vaccine storage & handling or transport, may result in vaccine loss.

When a vaccine storage unit will undergo maintenance or repair, contact VDH in advance for instructions regarding vaccine storage during the repair work.

B. Alternate storage location

1. Determine a suitable back up location with a generator for vaccine storage in the event of a mechanical or power failure. An extended power outage is defined as lack of power for more than 2 hours.
2. This location CANNOT be a private home. The unit must be able to accommodate the amount of vaccine currently in storage and meet requirements outlined in this plan. Consult with the management at the alternate site to assure your vaccine can be appropriately stored, if needed.
3. Permission from the Immunization Program is required prior to moving state supplied vaccine

C. Emergency plan for a power outage

NEVER move vaccine to a home, another storage unit, or to an approved location without permission from the Immunization Program. In many cases it is better to leave vaccine where it is during a power outage rather than move it. If the building has lost electrical power, check with building maintenance or the power company to learn if a time for the restoration of power can be determined.

1. **During a short-term power outage (2 hours or less)**
   - Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range.
   - If the outage occurs during business hours, note the time of the power failure.
   - Once power has been restored, note the time and monitor the temperature until it reaches 2°to 8°C for the refrigerator and -50° to -15°C for the freezer.
   - Determine if the temperature has been out of range; if yes, contact the Vermont Immunization Program.

2. **During a long-term power outage (greater than 2 hours)**
   - Do not open the refrigerator or freezer door unless approval is requested and received from VDH to transport vaccines to the backup location.
   - If instructed to move vaccine to your alternate location:
     - Contact the alternate location to ensure their power is functional and that they can store vaccine. If they do not have power or enough space to store this vaccine, contact VDH for assistance in finding another location.
     - Follow the instructions from the Immunization Program on packing and transporting vaccine. http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
   - NOTE: Varicella (including both varicella and MMR-V) vaccines are extremely temperature sensitive and moving these is usually not permitted.

Never transport vaccine unless authorized by VDH Immunization Program Staff. Vaccine stored in the freezer is NOT usually transported.

D. SensoScientific Alarm Notifications

Alarm	Meaning	Conditions	Action Required of Practice During Normal Business Hours	Action Required After Standard Business Hours
Data Alarm	Temperature is out of range.	The alarm will occur if the unit has been out of range for 45 minutes.	• Contact the Immunization Program. • Login into the cloud system and confirm the alarm under the Monitoring tab after the issue has resolved. • Do not suspend the alarm notification until the issue is resolved and instructions are provided by the Immunization Program.	• Contact the on-call person for guidance if you need to use the vaccine before the next business day or if you need to move the vaccine.
Signal Alarm	Internet connection has been lost.	When the Wi-Fi is off for 2 hours, the data will download once the connection is reestablished, unless the data logger has been reset.	• Wait 60 minutes for the connection to reestablish. If it has been longer than 60 minutes, contact the Immunization Program. • Login into the cloud system and confirm the alarm under the Monitoring tab after the issue has resolved. • Do not suspend the alarm notification until the issue is resolved and instructions are provided by the Immunization Program.	• No action required outside standard hours of operations. • If the network failed to reconnect, contact the Immunization Program the next business day.
Battery Alarm	The batteries are low.	Batteries need to be replaced.	• The practice is responsible for purchasing replacement batteries. Data loggers use four 1.5V AA Lithium Batteries. • If you need help with replacing the batteries, contact the Immunization Program. • Login to the cloud system under the Monitoring tab to confirm an alarm after you replace the batteries.	• No action required outside hours of operations. • Replace the batteries on the next business day.
Audible Alarm	Only if your audible alarm is enabled, then the data logger will sound off for the above noted reasons. Press the middle button to temporarily turn it off or login to the SensoScientific cloud system to permanently turn it off.			

Confirm the alarm only after the issue is resolved. Once a unit alarms, it will stay red until you confirm the alarm, even if the unit is reconnected to Wi-Fi, goes back into temperature range or the battery is replaced.

II. Rationale

Providers enrolled in the VCVP and state VAVP programs are entrusted with publicly funded vaccine and must ensure viability. Vaccine that is not stored under required conditions may be ineffective at producing an immune response. In 2019, the value of vaccine distributed to VCVP and/or VAVP enrolled practices in Vermont was more than $15,000,000.

III. Roles and Responsibilities

A. Vaccine coordinators

Designate a Primary Vaccine Coordinator and at least one Backup Vaccine Coordinator. These personnel are responsible for managing state-supplied vaccine, as described in this plan. Both should be knowledgeable about vaccine management, and the Backup should be capable of fulfilling all vaccine storage and handling requirements.

When the Primary Vaccine Coordinator or the Backup is replaced, notify VDH so that the required training can be scheduled promptly.

Training: The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VCVP/VAVP compliance site visit for the calendar year or if they were not present for the duration of the site visit.

1. You Call the Shots: Module 10, Storage and Handling
2. You Call the Shots: Module 16, Vaccines for Children Program [VFC providers only]

Find the modules at https://www.cdc.gov/vaccines/ed/youcalltheshots.html

B. Other staff

All staff with vaccine storage and handling responsibility must read and sign (on the cover page) this Vaccine Storage and Handling SOP annually *and* when changes are made to the plan.

IV. Storage and Handling-Best Practices

A. Selecting storage units (refrigerators and freezers) that will reliably maintain a safe temperature

1. Stand-alone refrigerators and freezers are strongly recommended over combination units.
2. Combination refrigerator/freezer units must have separate doors and should have separate temperature controls for each section. Use of such units is discouraged due to documented problems managing frozen vaccine and refrigerated vaccine in this style unit.
3. Never Permitted: Dormitory or bar-style refrigerators. These are small combination refrigerator/freezer units outfitted with one exterior.
4. Freezer
   - The freezer should be auto defrosting or self-defrosting.
   - Stand-alone freezers are strongly recommended. NIST[1] studies have shown that the freezer in a combination unit is unreliable for keeping frozen vaccine at the proper temperature.
   - Freezer temperatures must be maintained between -50°C and -15°C (-58°F and +5°F).
5. Refrigerator
   - Stand-alone refrigerators are strongly recommended. Refrigerated vaccine may be stored in a combination unit; preferably the freezer section is not used.
   - Refrigerator temperature must be maintained between 2°C and 8°C (36°F and 46°F).
6. Consider the following to determine what size unit is required:
   - Vaccine should not be stored in the door, crisper or in the space created by removing the crisper bins.
   - Vaccine should not be placed on the floor of the unit.
   - Vaccine should not be stored near a cooling fan or vent.
   - Keep vaccine at least 2-3 inches away from the walls, floor, coils of the storage compartment.
   - Place vaccine as centrally as possible in the unit to allow for air circulation.
   - Allow air space between each large package, block, tray, or bin of vaccines.
   - There should be enough room to accommodate the largest inventory of the year – typically during flu season (or back-to-school) – without over-crowding.
   - There should be space for water bottles marked “do not drink.” (See B.2 below.)
   - If medications and biologic materials need to be stored with vaccine, they should be placed below vaccine on a separate shelf to prevent possible contamination. They should not impede air flow.

[1] National Institute of Standards and Technology

- Keep vaccine away from cooling vents/fans if you use a combination refrigerator/freezer unit. Place water bottles in front of such vents, but don't block air circulation.
- Avoid use of the top shelf of the combination refrigerator when possible.
- Keep all vaccine vials/syringes in their original closed boxes, including opened multi-dose vials.
- It is best to store each type of vaccine in a separate, labeled basket or tray. Mesh containers are recommended over solid-sided ones because they allow for airflow. If solid-sided containers are used, they cannot have a lid.

B. Preparing the unit for vaccine storage

1. Do not store food and beverages in a vaccine unit.
2. Water bottles marked "Do Not Drink" can be placed in the refrigerator as a thermal buffer to help protect vaccine from temperature variations. Place them in the door and on the floor. Place against the back and along the walls if possible.
3. Frozen water bottles can be placed in the freezer as a thermal buffer. Place these in the door and on the floor. Also, place frozen water bottles against the back and walls if possible.
4. A "Do Not Disconnect" notice must be posted next to every outlet where a vaccine freezer or refrigerator is plugged in. A second "Do Not Disconnect" sticker must be posted on or near the corresponding circuit breaker.[2]

Unit Approval

Prior to use for storage of vaccine, the unit(s) should be inspected by Immunization Program staff and have at least 3 consecutive days of in-range temperatures, as monitored by a data logger supplied by the Immunization Program.

C. Vaccine transport (transfers)

All vaccine transport/transfers must be pre-approved by the Vermont Immunization Program.

Transport involves the movement of vaccine over a short time frame and distance between providers. The time needed to transport should be less than 8 hours and vaccine should be placed in a stable storage unit as quickly as possible. Vaccines should only be transported when absolutely necessary (in an emergency, or to ensure vaccines that are about to expire can be used rather than wasted). Frozen vaccine should never be transported except in an emergency with prior approval.

[2] These are available from VDH.

Supplies each practice must have on site in order to transport vaccines safely:

- Hard sided container or Styrofoam
- Backup data logger (see section D)
- Frozen water bottles (that need to be conditioned prior to packing)
- Insulating materials such as corrugated cardboard and bubble wrap (enough for two layers per container)

Follow instructions on packing and transporting refrigerated vaccine at http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
Instructions on packing frozen vaccine for transport are provided with prior approval from the Vermont Immunization Program.

Never place vaccine directly on frozen water bottles or frozen ice packs.

D. Backup data loggers

Backup data loggers are required to be used if an on-site data logger malfunctions, during vaccine transport, and for off-site vaccination clinics. The Vermont Immunization Program provides backup data loggers to all VCVP/VAVP enrolled practices. Practices have a backup data logger on site. For additional data loggers contact the Immunization Program.

Backup data loggers:

- Need to be stored in a documented location in the white box
- Ensure at least one computer has the current LogTag software installed https://logtagrecorders.com/software/lta3/download/
- Cradle to download the data logger

Backup data logger setup prior to use:

1. Condition the glycol bottle to the appropriate temperature by placing it in the fridge/freezer.
2. Once in range you may package the vaccine according to instruction (see section C).
3. Transport the vaccine.
4. If the data logger stays in range for the entire length of transport, no further communication with the program is needed.
5. If the data logger goes out of range during transport OR it was never able to get into proper range due to time constraints, you **MUST contact the program** and report this as a temperature excursion.

E. Proper Vaccine Placement

Vaccine to store in the freezer	Vaccine to store in the freezer *or* refrigerator	Vaccine to store in the refrigerator
✸ Varicella ✸ MMRV	✸ MMR *Freezer is preferred.*	✸ All others
Diluent	✸ Diluents that are packaged with their vaccines (e.g. ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed. ✸ Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, *not in the freezer*. This includes diluents for MMR, MMR-V, and Varicella.	

1. Avoid administration errors
    - Label each basket/tray with the vaccine type. Labels are available for printing at https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf
    - Separate and label privately-purchased vaccine vs. state-supplied vaccine.
    - Separate and label adult vs. pediatric vaccine.
    - On a multi-dose vial, mark the date it is opened. It should be used through manufacturer's expiration date printed on the vial.
    - Conduct weekly inventory to ensure rotation of vaccines. Short dated vaccine must be used first.
    - Report vaccine administration errors to http://verp.ismp.org/

F. Temperature monitoring

- **Thermometers:** Storage unit temperatures must be continuously monitored using data loggers purchased and installed by the Vermont Immunization Program.
- **Placement:** The probe in glycol bottle must be placed centrally in the storage unit.
- **Calibration:** Vaccine thermometers must have a current certificate of calibration. VDH is responsible for recalibration services.
- **Malfunction:** If a data logger malfunctions call the Immunization Program immediately.

2. **Daily**, each day the clinic is staffed, for each vaccine storage unit:
   - At the **start of each clinic day**, login to the SensoScientific cloud system, check off each vaccine storage unit and click "Audit Node." By doing Audit Node daily, you are documenting maximum and minimum temperatures only as well as the time and name or initials of the person taking the reading.
   - The **refrigerator** temperature must be between **2°C and 8°C** (36°F - 46°F).
   - The **freezer** temperature must be between **-50°C and -15°C** (-58°F to 5°F).

Strive for 5°C	Freezer temperature
The refrigerator must be between 2°C and 8°C. *Strive for an average reading of 5°C.*	The freezer must be between -50°C and -15°C.

ALARM
Take action if the unit is alarming.

V. Inventory management and ordering vaccine

A. Vaccine ordering schedule

1. Each practice is assigned an ordering frequency with a 2-week window of time.
2. If the practice runs out of vaccine before the next scheduled order, call the Immunization Program to discuss placing an additional order.
3. If there is not enough space in your refrigerator or freezer to store vaccine as described in this document, the unit is too small. Request an increased ordering frequency and consider the purchase of a unit that can store the largest anticipated inventory.

B. VIMS and Vaccine ordering

1. VIMS is accessed through the Vermont Immunization Registry (IMR) found here: http://www.healthvermont.gov/health-statistics-vital-records/registries/immunization.
   - To reach VIMS, users must have IMR access. Users who do not have or do not know if they have IMR access, should contact IMR support at 888-688-4667.
   - Once logged in, Select "Vaccine Inventory Management System (VIMS)" from the left navigation menu.
2. A step-by-step VIMS User Guide is available on the Immunization Program website: http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_vax_ordering_User%20Guide.pdf
   - **Flu vaccine:** Flu vaccine is ordered by the Immunization Program for all practices, beginning the first week of Sept. Specific guidance will be provided annually in August.
3. All vaccine orders are reviewed by the Immunization Program. Should adjustments be necessary, you will be contacted.
4. Status and tracking information for vaccine orders can be checked using the View History link.

C. Receipt of vaccine shipments

1. Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines (varicella and MMR-V) are shipped by the manufacturer, Merck.
2. Upon receipt of **refrigerated** vaccines, open the box and check the enclosed temperature monitoring card. If it shows that an out-of-range temperature occurred during shipping, mark the vaccine "do not use," immediately store it in the refrigerator and call McKesson Specialty at 1-877-836-7123 *the same day*, for further instructions.
3. **Frozen** vaccines are NOT packed with temperature indicators. Instead, they come with a shipper insert that identifies the allowable shipping time. Check the packing slip's shipping date to determine how long the vaccines were in transit. If the shipment arrived beyond the

allowed time, mark the vaccine "do not use", store it in the freezer, then call the Immunization Program.

- The lid of the box contains diluent. Remove the diluent from the lid before you discard the box. Diluent can be stored in the refrigerator or at room temperature, but not in the freezer.

4. Verify that the packing slip agrees with the content of the shipment. Date and sign the packing slip and keep it for your records. Do not fax it to VDH.
   - If the contents of the shipment and the packing slip do not match, call the Immunization Program *the same day* the shipment is delivered.
5. Rotate vaccine stock within storage units to ensure that vaccines with the shortest expiration dates are placed in a position to be used first.

D. Avoiding wastage due to vaccine expiration

1. Conduct a weekly inventory to ensure that vaccine with earliest expiration date is used first.
2. Sixty to 90 days prior to expiration, if vaccine is not likely to be used, contact the Immunization Program for assistance redistributing the vaccine to a practice that can use it. Immunization Program permission is required prior to moving state supplied vaccine.
3. **Remove** expired or non-viable vaccine from the storage unit. Mark "Do Not Use". Refer to the Section F for instructions.

E. Maintaining the integrity of state-supplied vaccine stocks

Never borrow (swap) vaccine between state-supplied and private vaccine stock.

F. Handling expired, spoiled, and wasted vaccine

All spoiled, expired or wasted vaccines must be accounted for and reported to the Immunization Program in VIMS. These doses are documented via an Adjust Request with an Adjustment Type of Return or Waste.

1. **RETURN** Non-viable, unopened and intact state-purchased vaccine vials and syringes should be returned to McKesson for federal excise tax credit.
   - All expired or spoiled vaccine must be reported in a VIMS Adjust Request. Print the Request to use as a packing slip.
   - The Immunization Program will review the Request and, upon approval, UPS will email the user a shipping label.

- Upon receiving the shipping label, vaccine should be packed to prevent vial breakage and shipped to McKesson within six months of spoilage or expiration. Enclose the Request print out as a packing slip.

2. **WASTE** Vaccines are considered wasted if they have been opened or damaged and cannot be administered to patients. These vaccines may not be returned and should be discarded as medical waste.

   - Reasons for waste include: being drawn into a syringe but not administered, opened in error, error in reconstitution, vaccine whose sterility has been compromised by the vial being dropped or broken or open multi-dose vials that have expired.
   - All wasted vaccine must be reported in a VIMS Adjust Request.
   - Dispose of wasted vaccine on site in a sharps container.

The Immunization Program greatly appreciates and values the many significant contributions of Vermont primary care practices in ordering, storing, handling and administering immunizations to children, adolescents and adults.